UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

KIRBY KNIGHT and
SHIRLEY KNIGHT,

Plaintiffs,

Hon. Janet T. Neff

v.

Case No. 1:09-CV-973

ST. JUDE MEDICAL,

Defendant.
_____/

REPORT AND RECOMMENDATION

This matter is before the Court on Defendant St. Jude Medical, Inc.'s Motion to Dismiss Plaintiff's Amended Complaint. (Dkt. #25). Pursuant to 28 U.S.C. § 636(b)(1)(B), the undersigned recommends that Defendant's motion be **granted in part and denied in part**.

BACKGROUND

The following allegations are contained in Plaintiffs' amended complaint. (Dkt. #21). On June 17, 2002, Kirby Knight received a St. Jude Medical internal cardiac defibrillator (ICD) with Riata lead. On May 22, 2006, an examination of Knight's pacemaker, by Hal Gorski, R.N., revealed "problems." As a result, Gorski contacted St. Jude Medical, which sent a "representative" to further assess the matter. This representative "adjusted [Gorski's] equipment so that he could interrogate" Knight's pacemaker. The representative "also stated that he had some concerns about the lead insulation," but that the pacemaker was "functioning properly" and that Knight "was in no danger."

However, the representative "refused to state specifically what the problem was or to give Plaintiffs any written record of this." Kirby Knight's treating physicians "relied upon these reassurances from the St. Jude Medical Rep." On September 11, 2006, Knight's pacemaker was "again interrogated" and Plaintiffs were "again assured that all was well and that they had nothing to worry about."[1]

According to Plaintiffs, "the interrogations of May and September, 2006, revealed to the defendant information and data indicating that the defibrillator/ICD of the unit would not function, which the defendant, St. Jude Medical, knew or should have known at that time, and should have revealed to the Plaintiffs and Mr. Knight's health care providers." Plaintiffs also allege that "despite numerous requests for the data and information from said interrogations, this information was not provided to the plaintiffs by the defendant, thereby withholding knowledge of the dysfunctional status of the defibrillator from the plaintiffs and Mr. Knight's treating physicians." Plaintiffs further allege that "defendant knew or should have known that the plaintiffs and Mr. Knight's treating physicians would rely upon their representations that the unit was functioning properly, and that future decisions relating to Mr. Knight's medical care and treatment, including whether or not and when to replace the unit, were being made on the basis of these representations."

On October 8, 2006, Kirby Knight was transferred from Reed City Hospital to Spectrum Health in Grand Rapids, following a heart attack. On October 15, 2006, Knight, who was still hospitalized, "suffered a ventricular fibrillation episode causing his heart to stop." Because Knight's pacemaker/ICD "failed to fire," hospital personnel were "required to perform CPR upon Mr. Knight, give an injection of Epinephrine, and to shock him once with the hospital's external defibrillator." These actions "restarted" Knight's heart, by which time, however, he had experienced "prolonged cessation

[1] At hearing, Plaintiffs' counsel conceded that Defendant's representative was *not* present during this incident.

of blood flow to the brain, depriving the brain of proper oxygenation for more than five minutes, resulting in cerebral hypoxia which caused [Knight] to sustain permanent, catastrophic, and debilitating medical consequences."

According to treatment notes authored by Physician's Assistant, Teresa Wainscott and Dr. Mark Koets, "the cardioverter did not fire during the v-fib arrest of October 15, 2006. . .there was a dead battery, and. . .the pacemaker needed to be changed." On October 16, 2006, Knight's pacemaker was replaced by Dr. Woefil. Prior to this procedure, "numerous personnel" from St. Jude Medical arrived at the hospital and conducted "a complete interrogation" of the pacemaker "before it was removed from Mr. Knight's body."

During this process, "[v]olumes of data being extracted from the unit passed across their computer screen." When Plaintiffs asked "for a copy of the interrogation data," they were informed by "St. Jude Medical technicians" that the information "would take over 100 pages to print but that St. Jude Medical would supply [Knight] with a complete printout." Despite "numerous subsequent requests," the data was never supplied to Plaintiffs. During this interrogation process, "Plaintiffs and their daughters" observed a "computer screen pop-up which stated something to the effect that the pacemaker was functioning, and that the defibrillator was non-functioning." Dr. Woefil theorized that the failure of Knight's pacemaker "was most probably due to a lead fracture of the Riata lead."

When Plaintiff's pacemaker was surgically replaced, the faulty Riata lead was not removed. On October 22, 2009, an attempt to remove the lead was attempted. During this procedure, the lead "broke off, leaving a portion of the lead still inside" Kirby Knight's body.

In January 2007, Plaintiffs, in an attempt to receive a copy of the "interrogation data," contacted Defendant, which responded that there existed no such data because "the ICD would simply

not communicate." In correspondence dated March 16, 2007, Defendant reiterated that "St. Jude Medical was absolutely unable to download any information from the device on October 16, 2006 because the ICD would simply not communicate." These assertions contradict what Plaintiffs themselves observed.

In April 2009, Plaintiffs shipped "the ICD unit in question" to Defendant "for interrogation." Defendant thereafter "responded to plaintiff's request and supplied the interrogation data, as well as an interrogation report, which, compared with the same data previously supplied at Reed City Hospital in May 2006, demonstrated numerous material changes in the raw data, as well as false and fraudulent reports as to purported medical events preceding the v-fib arrest of October 15, 2006, and blatantly contradicting the Spectrum Health records."

Plaintiffs initiated the present action, asserting numerous claims against Defendant St. Jude Medical. Plaintiffs assert that St. Jude Medical "breached its duty of care" to Plaintiff Kirby Knight and exhibited numerous forms of negligence. Specifically, Plaintiffs allege that Defendant was negligent in the following ways:

1. Failing to provide adequate warnings, instructions, directions, recalls to the public and true information with regard to the safety and danger of the device to the applicable medical community and the plaintiff Kirby Knight;

2. Failing to adequately design, manufacture, assemble, test assemble, and service, sell and/or recall said defibrillators and/or Riata lead that show the probability of failure should the device be called upon to save the life of the recipient;

3. Failing to provide adequate safety procedures or to follow accepted explanation protocols dictated by data interrogated from the Photon ICD with respect to lead

fracture, low lead impedance, dangerous drops in battery voltage, and/or failure of the defibrillator;

4. Failing to adequately design, manufacture, assemble or sell said product in a condition reasonably safe for its intended and foreseeable uses;

5. Failing to adequately test and inspect said product to ensure that it was reasonably safe for its intended and foreseeable uses;

6. Failing to provide Plaintiff, Kirby Knight with truthful medical data, important to his well being, which Defendant knew or should have known would be relied upon by Plaintiffs and Mr. Knight's physicians, including the significance of lead impedance dropping below 200, Plaintiff Knight's lead impedance continuing to drop to 125, and the dramatic drop in battery voltage, as predicted by the Doctor's Advisory sent by the Defendant to cardiologists with a caution to watch the lead but failing to instruct physicians to replace these units under these circumstances.

7. Fraudulently, negligently, and/or wrongfully withholding data that was retrieved from Plaintiff's Unit by Defendant St. Jude Medical in the Spectrum Health Center on October 16, 2006, and then materially altering or otherwise misrepresenting said data, which denied Plaintiffs and his physicians the opportunity to make informed and time-critical medical decisions, and in an attempt to cover-up a breakdown of the lead which now leaves Knight in danger of having the piece of lead break loose and go into his heart killing him which is causing severe mental anguish and anxiety.

Plaintiffs assert that Defendant engaged in conspiracy to defraud by "having in place a protocol to fabricate medical records to cover-up problems evidenced by data stored within said Units and extracted by interrogation." Plaintiff asserts that Defendant conspired to, and actually materially altered, Kirby Knight's medical records and constructed and distributed false medical information that

could endanger Knight's life. Plaintiffs assert that Defendant omitted, altered, and/or destroyed "valuable patient health records in an attempt to cover-up a device malfunction that detrimentally impacted the health, physical well-being, medical treatment and care of" Kirby Knight. Plaintiffs assert that the aforementioned acts and omissions constitute negligence, fraud, negligent misrepresentation, gross negligence, reckless endangerment, and were a proximate cause of the catastrophic injuries suffered by Kirby Knight. Plaintiffs also assert a loss of consortium claim. Defendant now moves to dismiss Plaintiffs' claims on the ground that such fail to state a claim on which relief may be granted.

STANDARD

A Rule 12(b)(6) motion to dismiss for failure to state a claim on which relief may be granted tests the legal sufficiency of a complaint by evaluating the assertions therein in a light most favorable to Plaintiffs to determine whether such states a valid claim for relief. *See Bower v. Federal Exp. Corp.*, 96 F.3d 200, 203 (6th Cir. 1996).

To prevail on a Rule 12(b)(6) motion, Defendant must demonstrate that it appears beyond doubt that Plaintiffs can prove no set of facts in support of their claims that would entitle them to relief. As the Supreme Court stated in *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544 (2007), a motion to dismiss will be denied only where the "[f]actual allegations [are] enough to raise a right for relief above the speculative level on the assumption that all of the complaint's allegations are true." *Id.* at 545.

As the Supreme Court more recently held, to survive a motion to dismiss, a complaint must contain "sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, - - - U.S. - - -, 129 S.Ct. 1937, 1949 (2009). This plausibility standard "is not akin to a 'probability requirement,' but it asks for more than a sheer possibility that a defendant has acted

unlawfully." If the complaint simply pleads facts that are "merely consistent with" a defendant's liability, it "stops short of the line between possibility and plausibility of 'entitlement to relief.'" *Id.* As the Court further observed:

> Two working principles underlie our decision in *Twombly*. First, the tenet that a court must accept as true all of the allegations contained in a complaint is inapplicable to legal conclusions. Threadbare recitals of the elements of a cause of action, supported by mere conclusory statements, do not suffice. . .Rule 8 marks a notable and generous departure from the hyper-technical, code-pleading regime of a prior era, but it does not unlock the doors of discovery for a plaintiff armed with nothing more than conclusions. Second, only a complaint that states a plausible claim for relief survives a motion to dismiss. . .Determining whether a complaint states a plausible claim for relief will, as the Court of Appeals observed, be a context-specific task that requires the reviewing court to draw on its judicial experience and common sense. But where the wellpleaded facts do not permit the court to infer more than the mere possibility of misconduct, the complaint has alleged - but it has not "show[n]" - "that the pleader is entitled to relief."

Id. at 1949-50 (internal citations omitted).

When resolving a motion to dismiss pursuant to Rule 12(b)(6), the Court may consider the complaint and any exhibits attached thereto, public records, items appearing in the record of the case, and exhibits attached to the defendant's motion to dismiss provided such are referenced in the complaint and central to the claims therein. *See Bassett v. National Collegiate Athletic Assoc.*, 528 F.3d 426, 430 (6th Cir. 2008); *see also*, *Continental Identification Products, Inc. v. EnterMarket, Corp.*, 2008 WL 51610 at *1, n.1 (W.D. Mich., Jan. 2, 2008) ("an exhibit to a pleading is considered part of the pleading" and "the Court may properly consider the exhibits. . .in determining whether the complaint fail[s] to state a claim upon which relief may be granted without converting the motion to a Rule 56 motion"); *Stringfield v. Graham*, 212 Fed. Appx. 530, 535 (6th Cir. 2007) (documents "attached to and cited by" the complaint are "considered parts thereof under Federal Rule of Civil Procedure 10(c)").

ANALYSIS

I. Federal Preemption

While the federal government can exercise only those powers expressly identified in the Constitution, *see Marbury v. Madison*, 5. U.S. (1 Cranch) 137 (1803), the states, pursuant to their police powers, may act to promote the safety and welfare of their citizens so long as such action does not run afoul of the Constitution. *See, e.g., Gade v. National Solid Wastes Management Ass'n*, 505 U.S. 88, 108 (1992); *Kelley v. Johnson*, 425 U.S. 238, 247 (1976).

One of the limitations on a state's authority to act derives from the Constitution's Supremacy Clause, which provides, in relevant part, that "This Constitution and the Laws of the United States[2] which shall be made in pursuance thereof. . .shall be the supreme Law of the Land." U.S. Const., art. VI. Accordingly, when there exists a conflict between federal law and state law, the latter is rendered invalid. *See Gade*, 505 U.S. at 108 ("under the Supremacy Clause, from which our pre-emption doctrine is derived, 'any state law, however clearly within a State's acknowledged power, which interferes with or is contrary to federal law, must yield'").

A federal law can preempt state law implicitly or expressly. *See State Farm Bank, FSB v. Reardon*, 539 F.3d 336, 341 (6th Cir. 2008) (citation omitted). Implicit preemption is subdivided into two categories: conflict preemption and field preemption. *Id.* at 342 (citation omitted). Conflict preemption exists "where compliance with both federal and state regulations is a physical impossibility, or where state law stands as an obstacle to the accomplishment and execution of the full purposes and

[2] The phrase "Laws of the United States," as used in the Supremacy Clause, encompasses both "federal statutes themselves and federal regulations that are properly adopted in accordance with statutory authorization." *City of New York v. FCC*, 486 U.S. 57, 63 (1988).

objectives of Congress." Field preemption exists when "the scheme of federal regulation is so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it." *Id.* Express preemption exists "where either a federal statute or regulation contains explicit language indicating that a specific type of state law is preempted." *Id.* at 341-42.

Where a federal law or regulation purports to expressly preempt a state law, the court must first identify the scope or extent to which the state law is preempted. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 484-85 (1996). While such analysis begins by examining the text of the relevant federal provision, such must be undertaken in the context of the following notions. The court must first "start with the assumption that the historic police powers of the States were not to be superceded by the Federal Act unless that was the clear and manifest purpose of Congress." *Id.* at 485 (citations omitted). The court must also remember that "the purpose of Congress is the ultimate touchstone in every preemption case." *Id.* (citations omitted).

A. Medical Device Amendments of 1976 (MDA)

The Federal Food, Drug and Cosmetic Act (FDCA), enacted in 1938, mandated that new drugs obtain approval by the Food and Drug Administration prior to introduction. *See Id.* at 475-76. However, the FDCA did not authorize federal oversight or control over the introduction of new medical devices. Regulation or control of new medical devices was instead a matter left to the States to address pursuant to their traditional police powers. However, as medical care began to rely more and more on "a vast array of medical equipment," concern was expressed about "the increasingly severe injuries that resulted from the failure of such devices." *See Id.* In response, Congress enacted the Medical Device Amendments of 1976 (MDA). *See Id.* at 476.

The MDA classifies medical devices into three categories based on their perceived risk. *See* 21 U.S.C. § 360c. Class I medical devices are those that (1) are not used to support or sustain human life or which are not of substantial importance in preventing illness; and (2) do not present a "potential unreasonable risk of illness or injury." 21 U.S.C. § 360c(a)(1)(A). Class I medical devices are subject to "General Controls" *Id.* Class II medical devices are considered potentially more harmful. While advance approval for such devices is not required, if a Class II device is "purported or represented to be for a use in supporting or sustaining human life," the manufacturer must comply with certain "special controls. . .necessary to provide adequate assurance of safety and effectiveness." 21 U.S.C. § 360c(a)(1)(B).

Class III medical devices are those, the safety of which cannot reasonably be assured by the aforementioned methods, and which either "present[] a potential unreasonable risk of illness or injury," or are "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health." 21 U.S.C. § 360c(a)(1)(C). Generally, before a Class III medical device can be sold or distributed, it must obtain pre-approval from the Food and Drug Administration (FDA). 21 U.S.C. § 360e. There exist two categories of Class III devices that are exempt from this "pre-approval" requirement: (1) those introduced for commercial distribution prior to enactment of the MDA, and (2) those which are "substantially equivalent" to such pre-existing devices. 21 U.S.C. § 360e(b)(1)(A).

The MDA also contains a provision which expressly serves to preempt certain claims concerning the "safety and effectiveness" of medical devices. This provision provides (in full) as follows:

(a) General rule

Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement--

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

(b) Exempt requirements

Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a) of this section, under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if--

(1) the requirement is more stringent than a requirement under this chapter which would be applicable to the device if an exemption were not in effect under this subsection; or
(2) the requirement--

(A) is required by compelling local conditions, and

(B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this chapter.

21 U.S.C. § 360k.

B. *Riegel v. Medtronic, Inc.*

In 1996, doctors discovered that Charles Riegel's right coronary artery was "diffusely diseased and heavily calcified." *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 320 (2008). Riegel underwent a coronary angioplasty procedure during which his doctor inserted an Evergreen Balloon Catheter. The doctor utilized this particular device, despite the fact that its "labeling stated that use was contraindicated for patients with diffuse or calcified stenoses." The catheter's labeling also warned that the catheter

"should not be inflated beyond its rated burst pressure of eight atmospheres." Riegel's doctor inflated the catheter beyond its rated burst pressure, however, causing it to rupture. Riegel was forced to undergo emergency coronary bypass surgery.

Riegel subsequently initiated a lawsuit in federal court alleging that the catheter in question was "designed, labeled, and manufactured in a manner that violated New York common law, and that these defects caused Riegel to suffer severe and permanent injuries." *Id.* The district court dismissed Riegel's common law claims on the ground that such were preempted by the MDA. *Id.* at 320-21. The dismissal of Riegel's claims was affirmed by the Second Circuit. *Id.* at 321. The United States Supreme Court agreed to hear the matter to consider "whether the pre-emption clause enacted in the Medical Device Amendments of 1976, bars common-law claims challenging the safety and effectiveness of a medical device given premarket approval by the Food and Drug Administration (FDA)." *Id.* at 315.

To answer this question, the Court identified two preliminary questions which must first be answered. The Court first observed that "[s]ince the MDA expressly pre-empts only state requirements 'different from, or in addition to, any requirements applicable. . .to the device' under federal law, we must determine whether the Federal Government has established requirements applicable to Medtronic's catheter." *Id.* at 321. The Court further noted that if the answer to the previous question was in the affirmative, "we must then determine whether the Riegels' common-law claims are based upon New York requirements with respect to the device that are 'different from, or in addition to' the federal ones, and that relate to safety and effectiveness." *Id.* at 321-22.

With respect to the first question, the Court observed that the premarket approval process "is specific to individual devices" and examines whether "a device offers a reasonable assurance of

safety and effectiveness." *Id.* at 322-23. If a device receives premarket approval it must be manufactured "with almost no deviations from the specifications in its [premarket] approval application" because the FDA has determined that "the approved form provides a reasonable assurance of safety and effectiveness." *Id.* at 323. Thus, the Court concluded that with respect to a medical device which has obtained premarket approval, the Federal Government has established requirements applicable thereto. *Id.*

As for the latter question, the Court adhered to its previously stated view that "common law causes of action for negligence and strict liability do impose 'requirement[s]' and would be pre-empted by federal requirements specific to a medical device." *Id.* at 323-34 (quoting *Lohr*, 518 U.S. at 512). The Court rejected Riegel's argument that "the duties underlying negligence, strict-liability, and implied-warranty claims are not pre-empted even if they impose 'requirements' because general common-law duties are not requirements maintained 'with respect to devices.'" *Id.* at 327. As the Court observed, Riegel's suit "depends upon New York's 'continu[ing] in effect' general tort duties 'with respect to' Medtronic's catheter." *Id.* at 327-28.

The Court emphasized, however, that state requirements are pre-empted under the MDA "only to the extent that they are 'different from, or in addition to' the requirements imposed by federal law." *Id.* at 330. Accordingly, the MDA's pre-emption provision "does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations" because "the state duties in such a case 'parallel,' rather than add to, federal requirements." *Id.*

C. Application of *Riegel* to Plaintiffs' Complaint

Defendant moves to dismiss Plaintiffs' products liability claims on the ground that fail to state a claim on which relief may be granted because they are preempted by federal law.

As noted above, Plaintiffs assert a variety of common law negligence claims. Defendant has submitted documents demonstrating that the medical device in question received premarket approval by the FDA on March 11, 2002. The parties stipulated at hearing that the device in question has obtained premarket approval from the FDA. Accordingly, the Court finds that the Federal Government has established requirements applicable to the device in question. The question, therefore, becomes whether Plaintiffs' various negligence claims seek to impose requirements that are "different from, or in addition to" those imposed by federal law.

To the extent that Plaintiffs challenge the design, warnings, instructions, directions, procedures regarding the device in question (i.e., the "form" of the device that was approved by the FDA), such claims are clearly preempted by federal law for the reasons articulated by the *Riegel* Court. Plaintiff acknowledged such at hearing. Accordingly, the undersigned recommends that Defendant's motion to dismiss be granted as to such claims. The Court turns, therefore, to Plaintiffs' claims that Defendant did not properly manufacture, assemble, test, inspect, or service the device in question.

As the *Riegel* Court observed, state requirements are pre-empted under the MDA "only to the extent that they are 'different from, or in addition to' the requirements imposed by federal law." Thus, the MDA's pre-emption provision "does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations" because "the state duties in such a case 'parallel,' rather than add to, federal requirements." Several courts, post-*Riegel*, have recognized this distinction. *See, e.g., Hofts v. Howmedica Osteonics Corp.*, 597 F.Supp.2d 830 (S.D. Ind. 2009) (finding state law

claims against medical device manufacturer were not preempted under the MDA because they "alleged failure to manufacture [the device] in accordance with the [premarket approval] issued by the FDA"); *Rollins v. St. Jude Medical*, 583 F.Supp.2d 790 (W.D. La. 2008) (finding preemption under the MDA inapplicable as to state law claims that defendants "failed to manufacture the [medical device] in accordance with FDA specifications"); *Purcell v. Advanced Bionics Corp.*, 2008 WL 3874713 (N.D. Tex., Aug. 13, 2008) ("the MDA does not preempt Plaintiffs' [state law] claims. . .which are predicated solely on violations of federal law"); *Covert v. Stryker Corp.*, 2009 WL 2424559 (M.D.N.C., Aug. 5, 2009) (recognizing that "certain of Plaintiff's [state law] claims 'relating to' the labeling, safety and/or effectiveness of the [medical device] may escape pre-emption under [the MDA], so long as they are premised solely upon [Defendant's] non-compliance with an applicable federal 'requirement,' whereas such claims that are premised on anything other than said non-compliance are expressly pre-empted").

This distinction is consistent with the purposes underlying the MDA, as well as the *Riegel* decision. As the *Hofts* court observed:

> The MDA, as *Riegel* explained, was intended to protect overall public health and safety by relying on an expert agency to balance overall costs and benefits of medical devices that may do much good and even save lives, but that might not always work as they are intended to work. As applied in *Riegel*, the MDA protects manufacturers who comply with federal requirements from civil liability based on different or additional standards imposed by states (including juries). But if the MDA were construed as Howmedica argues here, the legislation would be transformed into a grant of immunity from civil liability for manufacturers who violate those same federal requirements. That result was rejected by the Court in *Lohr*, and neither the MDA nor *Riegel* supports it.

Hofts, 597 F.Supp.2d at 838-39 (internal citation omitted).

To the extent, therefore, that Plaintiffs assert claims based *solely* on Defendant's failure to comply with federal standards or requirements, preemption under the MDA may be inappropriate.

For example, if Plaintiffs' claims are interpreted as asserting that Defendant failed to manufacture, assemble, test, inspect, or service the device in question pursuant to the standards articulated in the FDA's premarket approval, preemption does not appear to be appropriate. The question then becomes whether Plaintiffs' complaint is fairly interpreted as asserting claims based *solely* on Defendant's failure to comply with federal standards or requirements or instead seek to hold Defendant to a standard in addition to that arising under federal law.

While Plaintiffs' negligence claims clearly arise under state law, it is not clear from Plaintiffs' pleadings whether Plaintiffs are alleging that Defendant's negligence is evidenced by its failure to comply with federal law or instead some other standard (e.g., common law duty of care). As Defendant asserts, Plaintiffs have not stated that their claims are based on a failure to comply with federal law (i.e., FDA regulations or the requirements of the premarket approval). Such failure would appear to run afoul of the *Iqbal* Court's admonition that to survive a motion to dismiss, a complaint must contain "sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face'" and, moreover, that if the complaint pleads facts that are "merely consistent with" a defendant's liability, it "stops short of the line between possibility and plausibility of 'entitlement to relief.'" Furthermore, at hearing, Plaintiffs' counsel conceded that he has neither information nor evidence that Defendant violated or failed to comply with any FDA regulation or other federal law or standard. Counsel further conceded that he was not asserting any claim that Defendant violated FDA regulations.

Accordingly, to the extent that Plaintiffs assert claims that Defendant failed to properly manufacture, assemble, test, inspect, or service the device in question, the undersigned recommends that Defendant's motion to dismiss be granted as to such claims. Specifically, to the extent that such claims are not based *solely* on Defendant's alleged failure to comply with federal standards or requirements,

all such claims are preempted as described above. To the extent that such claims are not subject to federal preemption, such claims have been abandoned by Plaintiffs and, furthermore, fail to state a claim on which relief may be granted.

II. State Law Negligence Claims

In addition to the claims discussed in the preceding section, Plaintiffs assert various other negligence claims. Specifically, Plaintiffs allege that Defendant was negligent in that it failed to provide Kirby Knight with "truthful medical data" regarding the device in question. Plaintiffs also allege that Defendant failed to "provide adequate warnings, instructions, directions, recalls to the public and true information with regard to the safety and danger of the device" to "the applicable medical community." Plaintiffs further allege that Defendant acted negligently by "withholding data" that was retrieved from Plaintiff's pacemaker on October 16, 2006. Defendant asserts that these claims should be dismissed because it owed no duty to Plaintiffs.

Under Michigan law, to establish negligence a plaintiff must establish the following: (1) defendant owed plaintiff a duty; (2) defendant breached that duty; (3) causation; and (4) damages. *See Cummins v. Robinson Twp.*, 770 N.W.2d 421, 433 (Mich. Ct. App. 2009). Duty is defined as the "obligation to conform to a particular standard of conduct toward another so as to avoid unreasonable risk of harm." *Id.* at 433-34. Whether a defendant owes a duty to a plaintiff is a legal question for the court to resolve. *Id.* at 434. Defendant asserts that pursuant to the learned intermediary rule, it owes no duty to Plaintiffs.

The learned intermediary doctrine "is an exception to the axiomatic principle that a manufacturer has a duty to warn the user of known dangers inherent to its product." *Mowery v.*

Crittendon Hospital, 400 N.W.2d 633, 637 (Mich. Ct. App. 1986). The learned intermediary rule recognizes that patients rely on their doctor's expertise and advice when using a drug or medical device and, moreover, may not appreciate or even understand any warnings provided directly by the manufacturer. *See Brown v. Drake-Willock Int., Ltd.*, 530 N.W.2d 510, 516 (Mich. Ct. App. 1995); *Mowery*, 400 N.W.2d at 636-37; *Muszynski v. Automotive Chemical Corp.*, 1996 WL 33358101 at *7 (Mich. Ct. App., Sept. 17, 1996). It has also been recognized that "a duty to warn the user directly would cause undue interference with the relationship between doctor and patient." *Mowery*, 400 N.W.2d at 637. As the Michigan Court of Appeals has held:

> This Court recognized the rule in *Mowery v. Crittenton Hosp.* and held that the defendants, a hospital, a physician, a medical laboratory, and a drug company, were not liable to the plaintiffs, a patient and her spouse, because the drug in question could only be purchased with a prescription issued by a doctor. This Court stated:
>
> > To expect the average citizen to know if he or she should take the drug or when to stop taking it, or to understand the technical language so often necessary to explain the dangers of the drug, is unreasonable. This is the basis for the "learned intermediary" rule adopted by a majority of jurisdictions in cases involving therapeutic, diagnostic or curative drugs.
> >
> > Accordingly, in the absence of a clear legal duty imposed on defendant manufacturers to directly warn plaintiffs, plaintiffs have failed to state a claim upon which they may recover.
>
> We now hold that the reasoning and policy behind the learned intermediary rule applies not only to prescription drugs, but also to prescription devices such as dialysis machines. Under the learned intermediary rule, the hospital or physician was the proper recipient of necessary information or warnings, not plaintiff. As in *Mowery,* defendant manufacturers had no duty to warn plaintiff in this case because of the learned intermediary rule.

Drake-Willock, 530 N.W.2d at 516.

Accordingly, to the extent that Plaintiffs claim that Defendant failed to warn or provide information to them, such claims must be dismissed as Defendant owed no duty to Plaintiffs. As noted above, however, Plaintiffs not only allege that Defendant failed to adequately warn *them*, but also assert that Defendant withheld relevant information about the functioning of Knight's pacemaker from Knight's care providers. While Michigan courts do not appear to have *directly* addressed this issue, the *Mowery* court seemed to suggest the possibility that notwithstanding the learned intermediary doctrine a cause of action exists where the manufacturer in question failed to adequately warn the learned intermediary.

In 1981, Bonnie Mowery was suffering a cataract of the right eye. *Mowery*, 400 N.W.2d at 634. To treat this condition, Mowery's doctor proposed to remove the cataract from Mowery's right eye and replace the eye's natural lens with an artificial intraocular lens. *Id.* Mowery agreed to undergo the procedure after being informed of the risks. *Id.* at 634-35. Mowery subsequently suffered a "detachment of the lower loop keeping [her] intraocular lens in place." *Id.* at 635. Mowery's doctor decided to treat Mowery, in part, with Phospholine Iodide, an opthamologic therapeutic drug which "could prevent dislocation of the intraocular lens." The doctor explained to Mowery that one of the risks of using this drug was retinal detachment. Despite such risks, Mowery agreed to the prescribed treatment. Mowery later suffered a detachment of the retina, after which she sued her doctor and the drug's manufacturer "alleging negligence for the failure to adequately test and/or warn." *Id.*

The manufacturer subsequently moved for summary judgment. The trial court concluded that "even if defendants' testing of Phospholine Iodide was inadequate, it was not the proximate cause of plaintiff's injury." *Id.* at 636. The court concluded that "[w]hile adequate testing would have allowed defendants to effectively warn plaintiffs and the treating physician of the risks of retinal detachment,

[Mowery's doctor] already knew of its risks, but chose to prescribe the drug and informed plaintiffs of the risk." The matter was subsequently appealed to the Michigan Court of Appeals. *Id.*

After discussing at length the learned intermediary doctrine, the court observed that "the learned intermediary doctrine supports a duty to warn only the prescribing physician." *Id.* at 636-37. Accordingly, the court concluded that to the extent that Mowery sued the drug's manufacturers for failing to warn her of the drug's dangers, such claim "failed to a state a claim upon which [she] may recover." *Id.* at 638. As for Mowery's theory that the drug's manufacturers failed to adequately warn her doctor, the court affirmed the trial court's decision granting the defendants' motion for summary judgment on the ground that the evidence revealed that Mowery's doctor was aware of the risks associated with the drug but nonetheless chose to prescribe the drug in question. *Id.*

While the *Mowery* court did not specifically address whether Mowery's claim that she suffered injury as a result of the defendants' failure to adequately warn her doctor of the risks associated with the drug in question stated a claim on which relief may be granted, such certainly seems implicit in the court's decision. Likewise, other courts have held that the learned intermediary doctrine does not apply if the manufacturer failed to adequately warn the "learned intermediary." *See, e.g., In re Mentor Corp. ObTape Transobturator Sling Products Liability*, - - - F.Supp.2d - - -, 2010 WL 1664965 at *14 (M.D. Ga., Apr. 22, 2010) (applying Georgia law) ("the first step of the [learned intermediary] inquiry is whether the manufacturer provided the learned intermediary with an adequate warning");[3] *Tyler v. Bristol-Meyer Squibb*, 2010 WL 1664967 at *1-2 (D. Neb., Apr. 23, 2010) (applying Nebraska law) (recognizing that the learned intermediary doctrine does not apply if the device's manufacturer fails to

[3] The court continued, observing that "[i]f the warning is inadequate, the plaintiff must show that the deficient warning proximately caused the alleged injury to prevail; if the learned intermediary 'has actual knowledge of the substance of the alleged warning and would have taken the same course of action even with the information the plaintiff contends should have been provided,' then the plaintiff cannot establish causation." *Id.* In this respect, Plaintiffs allege that Defendant's failure caused his injury.

provide "reasonable instructions or warnings" to "prescribing and other health-care providers who are in a position to reduce the risks of harm in accordance with the instructions or warnings").

Here Plaintiffs allege, albeit inartfully, that Defendant failed to "provide adequate warnings, instructions, directions, recalls to the public and true information with regard to the safety and danger of the device" to Kirby Knight's care providers. Plaintiffs further allege that Defendant's failure in this regard caused Kirby Knight's various injuries. For the reasons discussed above, the Court finds that such states a claim on which relief may be granted. Accordingly, the undersigned recommends that Defendant's motion be denied as to such claims.

III. Negligent Misrepresentation and Fraudulent Misrepresentation

Plaintiffs allege that on May 23, 2006, a representative of Defendant "assured Plaintiffs that all was well with the device, that it was functioning properly, and that they had nothing to worry about." Plaintiffs allege that these comments constitute fraudulent misrepresentation and negligent misrepresentation.

Under Michigan law, the elements of fraudulent misrepresentation are as follows: (1) the defendant made a material representation; (2) the representation was false; (3) when the defendant made the representation, the defendant knew it was false, or made it recklessly, without knowledge of its truth as a positive assertion; (4) the defendant made the representation with the intention that the plaintiff would act upon it; (5) the plaintiff acted in reliance upon it; and (6) the plaintiff suffered damage. *See Petfreedom.com, L.L.C. v. Net Generation, Inc.*, 2009 WL 2382430 at *3 (Mich. Ct. App., Aug. 4, 2009). To establish negligent misrepresentation, Plaintiffs must demonstrate that they "relied to [their]

detriment on information provided without reasonable care by one who owed the relying party a duty of care." *Id.*

Plaintiffs' fraudulent misrepresentation claims fail because Plaintiffs have not alleged that the representations in question were made with the intent that Plaintiffs would rely on such. Plaintiffs' negligent misrepresentation claims fail because, as discussed above, Defendant owed no duty to Plaintiffs. The undersigned, therefore, recommends that Defendant's motion be granted as to these claims.

IV. Conspiracy to Defraud

Plaintiffs allege that Defendant "is also guilty of conspiracy to defraud by having in place a protocol to fabricate medical records to cover-up problems evidenced by data stored within said Units and extracted by interrogation." To state a claim for civil conspiracy, Plaintiff must allege the following: (1) a concerted action, (2) by a combination of two or more persons, (3) to accomplish a criminal or unlawful purpose or to accomplish a lawful purpose by criminal or unlawful means. *See Edwards Publications, Inc. v. Kasdorf*, 2009 WL 131636 at *7 (Mich. Ct. App., Jan. 20, 2009). The factual allegations in Plaintiffs' Amended Complaint, even taken as true, fail to satisfy this standard. Plaintiffs have instead merely asserted the legal conclusion that Defendant has engaged in an unlawful conspiracy. As noted above, such fails to state a claim on which relief may be granted. Accordingly, the undersigned recommends that Defendant's motion be granted as to this claim.

V. Loss of Consortium Claim

Plaintiffs each assert a claim for loss of consortium. Defendant asserts that such claims must be dismissed as they are merely derivative of Kirby Knight's primary claims. Defendant is correct that such claims are derivative of Knight's primary claims and that if such claims are dismissed, the loss of consortium claims must likewise be dismissed. *See, e.g., Anderson v. Saddle Creek Apartments, LLC*, 2010 WL 1052276 at *7 (Mich. Ct. App., Mar. 23, 2010). As discussed herein, however, the Court concludes that certain of Kirby Knight's primary claims go forward. Accordingly, the undersigned recommends that Defendant's motion be denied as to these claims.

CONCLUSION

For the reasons articulated herein, the undersigned recommends that Defendant St. Jude Medical, Inc.'s Motion to Dismiss Plaintiff's Amended Complaint, (dkt. #25), be **granted in part and denied in part**. Specifically, the undersigned recommends that Defendant's motion to dismiss be granted and Plaintiffs' claims dismissed, save for (1) Plaintiffs' claims that Defendant failed to "provide adequate warnings, instructions, directions, recalls to the public and true information with regard to the safety and danger of the device" to Kirby Knight's care providers; and (2) Plaintiffs' loss of consortium claims.

OBJECTIONS to this Report and Recommendation must be filed with the Clerk of Court within fourteen (14) days of the date of service of this notice. 28 U.S.C. § 636(b)(1)(C). Failure to file

objections within the specified time waives the right to appeal the District Court's order. *See Thomas v. Arn*, 474 U.S. 140 (1985); *United States v. Walters*, 638 F.2d 947 (6th Cir.1981).

Respectfully submitted,

Date: January 11, 2011

/s/ Ellen S. Carmody
ELLEN S. CARMODY
United States Magistrate Judge